

# Notice of Allowability

Application No.

09/618,361

Examiner

Chih-Min Kam

Applicant(s)

BALASUBRAMANIAM ET AL.

Art Unit

1653

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/17/03.
2. ☒ The allowed claim(s) is/are 40-45 and 47-52.
3. ☒ The drawings filed on 15 April 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

- 1 ☐ Notice of References Cited (PTO-892)
- 3 ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 5 ☒ Information Disclosure Statements (PTO-1449), Paper No. 4/4/03 3/20/01
- 7 ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 2 ☐ Notice of Informal Patent Application (PTO-152)
- 4 ☒ Interview Summary (PTO-413), Paper No. 1203
- 6 ☒ Examiner's Amendment/Comment
- 8 ☐ Examiner's Statement of Reasons for Allowance
- 9 ☐ Other

  
CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1608

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An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with David Jefferies on December 4, 2003.

**Examiner's Amendments to the Specification:**

Please delete the paragraph of the specification beginning at page 1, line 14 and replace with the following paragraph:

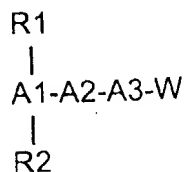
This application is a continuation-in-part of U.S. Application Serial No. 09/449,914, filed on December 2, 1999, now U. S. Patent No. 6,235,718, issued May 22, 2001, which is a divisional of U. S. Application Serial No. 08/907,403, filed on August 7, 1997, now U. S. Patent No. 6,013,633, issued January 11, 2000.

**Examiner's Amendments to the Claims:**

Claim 40 has been amended as follows:

40. (Currently Amended) A therapeutic composition comprising:

a therapeutically effective amount of a compound having the formula:



wherein:

each R1 and R2, independently, is H, C1-C12 alkyl, C6-C18 aryl, C1-C18 acyl, C7-C18 aralkyl, C7-C18 alkaryl or a dihydrotrigonellinate group;

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A1 is a D or L- amino acid selected from the group consisting of Cys, Leu, Dap, Trp, Gln, a tethered amino acid with an indole ring, Phe, Hyp, a derivative of Trp selected from the group consisting of N-Me-Trp, nor Trp, beta Me-Trp, 2-Cl-Trp, and 5-X-Trp<sub>1</sub> where X is selected from the group consisting of CN, Br, NH<sub>2</sub>, COOH, CH<sub>2</sub>NH<sub>2</sub> and CH<sub>2</sub>-CH<sub>2</sub>NH<sub>2</sub>; C $\alpha$ Me-Trp, C $\alpha$ Me-Gln, Des-amino-Trp, Pyr, Bth, Nal, Tcc, Asn, Nva, Abu, Tyr, Tic-OH, [Phe,] Tip, and Dip;

A2 is a D or L- amino acid selected from the group consisting of Cys, Trp, Arg, N $\alpha$ -Me-Arg, C $\alpha$ Me-Arg, Orn, Cit, hArg(R)<sub>2</sub>, where R is selected from the group consisting of hydrogen, alkyl, aryl, aralkyl, [or] and alkylaryl, Lys- $\epsilon$ -NH-R, where R is selected from the group consisting of alkyl, aryl, aralkyl, [or] and alkylaryl;

A3 is a D or L- amino acid selected from the group consisting of Glu, N-Me-Tyr, C $\alpha$ Me-Tyr, Tic-OH, Tic, Dip, Trp, Phe, des-carboxylic-Tyr (tyramine), and Tyr-(R), where R is hydrogen or lipophilic group;

W is OH, -N-R<sub>3</sub>R<sub>4</sub>, or OR<sub>5</sub>, where R<sub>3</sub>, R<sub>4</sub> and R<sub>5</sub>, independently, is H, C1-C12 alkyl, C6-C18 aryl, C1-C12 acyl, C7-C18 aralkyl, or C7-C18 alkaryl, or a pharmaceutically acceptable salt thereof; and

each bond between two amino acids or amino acid derivatives, represented by a dash ("-"), can be either a peptide bond or a pseudopeptide bond; and

a pharmaceutically acceptable carrier substance;

wherein said therapeutically effective amount of said compound in said composition attenuates Neuropeptide Y (NPY) mediated physical responses.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

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December 4, 2003

*Christopher S. F. Low*  
CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600